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10/598,334	08/24/2006	Leon Thomas Lee Marsh	78104113/N19108	2747

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EXAMINER

DOUGHERTY, SEAN PATRICK

ART UNIT

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3736

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/598,334	Applicant(s) MARSH, LEON THOMAS LEE	
	Examiner SEAN P. DOUGHERTY	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/24/2006, 09/10/2007</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

This is the *initial* Office action based on the 10/598334 application filed August 24, 2008. Claims 1-15 and 18 are currently pending and have been considered below.

Priority

If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 35 U.S.C. 119 (a)-(d) or (f), a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Claim 18 was added in the amendments filed August 24, 2008 which is after the original filing date of 08/24/2006. Examiner contends that the Applicant was not in possession of the "computer program for measuring hydration of a subject" at the original filing date of the application. A computer program and the computer code is critical or essential to the practice of the invention, but not included in

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the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The disclosure fails to mention the term “computer code” or even a “computer program”.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1-15 and 18, it is indefinite what hydration level is being determined. Examiner notes that hydration level could be one of several things, some examples are as follows: (a) hydration level prior to physical activity to determine how much hydration is required to ensure hydrated physical activity; (b) hydration level during physical activity to ensure that hydration level remains at an appropriate level; (c) hydration level after physical activity to ensure that a proper hydration levels are replenished. As demonstrated in (a) through (c), it is unclear what exactly the hydration level is because it is not known if it is simply an instant hydration reading of the body or is it a level of hydration required for proper physical activity.

Furthermore, the hydration monitor and equations to appear in claims 10, 11, 14 and 18 appears to only recite a hydration level determined by a vague equation. The validity of such determination of hydration by the equation is questioned by the Examiner, as many other factors that influence hydration levels including a subject's

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height, subject's age, subject's sex, subject's body fat content, subject's initial hydration level, subject's health status, subject's diet, et al., have not been considered in the equation. Additionally, evidence, calculations and empirical evidence are not found in the specification to allow the Examiner to determine why such calculation does not require additional body factors or why the equation is anything other than a rough calculation of a subject's hydration level. The Applicant's invention appears to simply use temperature readings to measure hydration levels without taking into account many other particular hydration factors. Therefore, the equation appears to be an ambiguous equation for determining an approximation or best guess of the subject's hydration level.

Lastly, it is unclear what the ambient compensation factor is as the specification recites two definitions:

d) The factor of ambient compensation may be between 0.1 and 0.23 and is determined in dependence on the temperature of the environment surrounding the subject [0043];

e) The factor of ambient compensation is valued between 0.1 and 0.23 degrees centigrade, and refers to the increase in the subject's core body temperature for every percent loss of body weight, in temperate and hot climates respectively [0064].

Additionally, both definitions and respective descriptions in the specification fail to establish how the factor of ambient compensation is determined because it is not disclosed how the factor between 0.1 and 0.23 degrees centigrade is chosen. One having ordinary skill in the art would not understand how to use the equation since he/she would not know how to pick the ambient factor between 0.1 and 0.23.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 14, 15 and 18 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

In order for a method to be considered a “process” under §101, a claimed process must either: (1) be tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials). See *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972). If neither of these requirements is met by the claim, the method is not a patent eligible process under §101, and therefore, is non-statutory subject matter.

The MPEP includes the Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility, which provides the procedure for determining patent eligible subject matter. The procedure is used as follows.

The first step of the procedure is to consider whether, as stated above, the process is tied to another statutory category.

In the present application, **claims 14 and 18** are drawn to a process - “a method of measuring hydration of a subject” and “a computer program for measuring hydration of a subject”. However, these claims are non-statutory because the claim language does not provide a sufficient tie to an apparatus that can be used to perform the claimed

steps. Note that claim 14 is not tied to an apparatus and claim 18 includes the use simply a computer signal on an undefined device, signals are non-statutory subject matter. Applicant should note that the preamble is not sufficient to provide such a tie.

Dependent **claims 15** merely add further details of the calculations recited in claim 14 and 18 without including any tie to another statutory category.

The next step in the procedure is to determine whether a judicial exception (i.e., abstract ideas, laws of nature, natural phenomenon) exists in the claims.

In the present application, claims 14 and 18 clearly include one of the judicial exceptions, in that the steps of claims 14 and 18 are nothing more than mental processes, or abstract ideas.

However, the analysis does not end here. While abstract ideas alone are not eligible, the claim as a whole must be analyzed to determine whether there exists a particular application of the abstract idea. That is, the claim must provide real-world, or practical application, of the abstract idea, law of nature, or natural phenomena. If such an application exists, the claimed invention is subject matter eligible, or statutory. Furthermore, in order for an invention to be patentable, it must be in compliance with the “useful invention” (“utility”) requirement of 35 U.S.C. 101 and 112, first paragraph.

Therefore, the claimed invention(s) must either: (1) transform an article or physical object to a different state or thing; or (2) produce a useful, concrete, and tangible result.

(1) Regarding claims 14 and 18, the claim language does not provide a transformation or reduction of an article to a different state or thing (entity).

(2) Accordingly, one must then also consider whether the claimed invention produces a (A) useful, (B) concrete, and (C) tangible result.

(A) For an invention to be "useful," the utility of the invention has to be (i) specific, (ii) substantial and (iii) credible. *See MPEP 2107*.

It can be argued that claims 14 and 18 do not provide a useful result in that the claim does not specify how the problem is solved; or that there is even a problem to actually solve.

(B) When determining whether the invention produces a "concrete" result, one is considering whether the process produces a result that can be substantially repeatable or substantially produce the same result again and again. Resolving this question is dependent on the level of skill in the art. For example, if the claimed invention is for a process which requires a particular skill to determine whether the process is substantially repeatable will necessarily require a determination of the level of skill of the ordinary skilled artisan.

In this present instance, claims 14 and 18 does not provide a result that can be assured in that the result can not be substantially repeatable and the process can not substantially produce the same result again.

(C) The tangible requirement requires that the claim must recite more than a 101 judicial exception, in that the process claim must set forth a practical application of the judicial exception to produce a real world result. Applicant should note that the tangible requirement does not necessarily mean that a claim must either be tied to a particular

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machine or apparatus or must operate to change articles or materials to a different state or thing. It does mean that the solution to a problem have to produce a real world result.

In this present instance, the claim language does not provide a solution to the problem with a real world result; that is the equations provided produce no real world result as the equation is claimed with no final outcome and does not provide a practical application.

In view of the above analysis, claims 14 and 18 are processes, which are not tied to another statutory category and include a judicial exception therein.

Accordingly, claims 14 and 18 are non-statutory.

Dependent claim 15 only includes the various steps thereof. Accordingly, the dependent claims are non-statutory as well.

See *In re Bilski*, Appeal No. 2007-1130 (Fed. Cir. March 6, 2008). See *In re Comiskey* No. 06-1286 (Fed. Cir. September 20, 2007; en banc).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 12 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,790,178 to Mault et al. (Mault).

Regarding claim 1, Mault discloses a hydration monitor (see Fig. 18) comprising a temperature sensor (thermistor; col. 18, lines 6-10) for measuring a subject's core body temperature (col. 17, lines 9-11) and a processor (PDA), the processor being arranged to accept measurements from the temperature sensor (col. 17, lines 11-16) and calculate a hydration level in dependence on changes in the measured core body temperature. Note that the PDA of Mault is capable of calculating hydration in dependence on changes in the measured core body temperature because the PDA monitors temperature of time and plots the subject's temperature over a time period (col. 17, lines 38-43).

Regarding claim 2, Mault discloses an earpiece and a remote unit ("an ear canal temperature measurement module interconnects with a PDA" col. 17, line 67 to col. 18, line 1), the temperature sensor being positioned in the earpiece for measuring the core body temperature via the subject's tympanic membrane (col. 18, lines 6-10).

Regarding claim 3, Mault discloses thermopile ("temperature responsive circuit such as a thermistor" col. 18, line 7).

Regarding claims 4, 5 and 6, Mault discloses where the earpiece further comprises a transmitter, the remote unit including the processor, output means and a receiver, the earpiece being arranged to communicate measurements to the processor via the transmitter and receiver, the processor being arranged to provide an indication of the hydration level via the output means, where the transmitter and receiver communicate wirelessly and where the transmitter and receiver are transceivers (col. 17, lines 21-24; col. 17, lines 56 to col. 18, line 3).

Regarding claim 7, Mault discloses where the remote unit comprises a selected one of: a wristwatch, a personal digital organizer, a mobile telephone, a personal computer or medical diagnostic and/or monitoring apparatus ("armband, headband, or the like" col. 17, line 60).

Regarding claim 8, Mault discloses where the output means includes one or more of a display and a speaker (note display on PDA in Fig. 18).

Regarding claim 9, Mault discloses a memory for storing hydration level and/or core body temperature over time ("memory modules" see Abstract).

Regarding claim 12, Mault discloses the hydration monitor arranged to operate repeatedly at predetermined time intervals ("the PDA monitors temperature over time" col. 17, line 17).

Regarding claim 13, Mault discloses where the processor is arranged to generate an alarm upon determination of a hydration level below a predetermined level (col. 17, lines 29-30).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 10, 11, 14 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mault as applied to claim 1, in view of EP 1,177,763 to Takehara et al. (Takehara).

Regarding claim 10, 11, 14, 15 and 18, Mault discloses the claimed invention, including where measurements are taken from the subject's tympanic membrane ("ear canal temperature measurement" col. 17, col. 17, line 67 to col. 18, line 1) as disclosed above. Mault does not expressly disclose a hydration level by the following formula:
$$\frac{[(\text{core body temperature current} - \text{core body temperature normal}) \cdot \text{subject's weight}]}{(\text{factor of ambient compensation} \cdot 100)}$$
 Kraemer teaches that it is known that bioelectric impedance values change as the body temperature changes ([0007] lines 23-26) and teaches a method for detecting a dehydration condition (see [0008]) using a device that includes body temperature sensors (see [0023]) including a method of calculating the hydration status of a subject (see [0021] to [0024]).

One having ordinary skill in the art at the time the invention was made would have found it obvious to use the method of detecting the hydration status of Takehara with the device of Mault. Note that Takehara teaches a method that takes into account

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several bodily factors to determine a hydration status, such a method is equivalent with the claimed calculations because they both produce an equivalent and practical result for determination of hydration status (Takehara: see Abstract).

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN P. DOUGHERTY whose telephone number is (571)270-5044. The examiner can normally be reached on Monday-Friday, 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. P. D./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736